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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,033	01/04/2006	Warren Ward	WAW0101PUSA	1595

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EXAMINER	
KASSA, TIGABU	
ART UNIT	PAPER NUMBER
1619	
MAIL DATE	DELIVERY MODE
06/23/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,033	WARD, WARREN	
	Examiner	Art Unit	
	TIGABU KASSA	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28,30-34,36 and 37* is/are pending in the application.

4a) Of the above claim(s) *1-6,12-23 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-11, 24-28, and 30-33, and 36-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the amendment filed April 05, 2010. **Claims 1-28, 30-34, and 36-37 are currently pending. Claims 7-11, 24-28, and 30-33, and 36-37 are under consideration in the instant office action.** Claims 1-6, 12-23, and 34 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claims. Claims 29 and 35 are cancelled. Applicant added new claim 37. Applicant's declaration submitted along with the response on April 05, 2010 is also acknowledged.

Maintained Rejections

Claim Rejections - 35 USC §101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The claimed invention lacks patentable utility. The instant application fails to provide adequate evidence to support the utility of the invention. Specifically, there is insufficient evidence to show that a compound which is not released on or into the body can have any medically beneficial effect. Additionally, the agents used to form the liquid impermeable but gas permeable layer (e.g. wax) are also used in the art to form controlled release formulations of drugs.

Response to Arguments

Applicant's arguments filed on April 5, 2010 have been fully considered but they are not persuasive. *Applicant argues that the examiner has not properly established a lack of utility.* This is not found persuasive since the examiner has explained that the medically efficacious

substances such as aspirin which are coated such as they are not released cannot have utility as a medicament. For example, Vane et al. (Inflamm Res 1995, 44, 1-10), Catella-Lawson et al. (New England Journal of Medicine 2001, 345, 1809-1817) teach that the mode of action of anti-inflammatory drugs is as cyclo-oxygenase (COX) inhibitors. Rashid et al. (Journal of Pharmacology and Experimental Therapy 2003, 304, 940-948) teach the mode of action of capsaicin is via the vanilloid receptor 1. They are incapable of inhibiting COX enzymes if they are coated such that they are not released. *Applicant argues that the examiner has not been receptive to application's express assertions of utility.* This is not found persuasive since the examiner has in fact considered applications arguments and asserstoin and has responded to said arguments by providing sound scientific reasoning to support the finding of lack of utility. *Applicant argues that he has provided mechanisms by which the claimed invention is believed to function specifically via communication with skin via gases in the surrounding environment.* This is not found persuasive since the mode of action of such medically efficacious substances as aspirin and capsaicin is via receptors; when they are not released, they cannot interact with those receptors. *Applicant argues that the lack of utility rejection is founded on the Examiner's belief and/or assumption that an invention must have a conventionally recognized mechanism of action, such as a cell receptor binding, that must not be contrary to the currently accepted scientific principles, to satisfy the utility requirement.* This is not found persuasive because In re Chilowsky, 229 F.2d 457, 461-2, 108 USPQ 321, 325 (CCPA1956) ("There appears to be no basis in the statutes or decisions for requiring any more conclusive evidence of operativeness in one type of case than another. The character and amount of evidence needed may vary, depending on whether the alleged operation described in the application appears to accord with

or to contravene established scientific principles or to depend upon principles alleged but not generally recognized, but the degree of certainty as to the ultimate fact of operativeness or inoperativeness should be the same in all cases") (From MPEP 2107.01). *Applicant argues that he has never suggested that the claimed invention can only function via cell receptor mediated signaling communication. Moreover, applicant argues that changes in external environment in proximity to the body cell surfaces may be calculated to elicit a response.* This is not found persuasive since receptor mediated modes of action are known and taught in the art. In contrast, applicant's invention does not even release the medically efficacious substance. There are well known uses for medically efficacious substances such as aspirin and related non-steroidal antiinflammatories, capsaicin, and the other actives claimed to be contained within the instant preparation. However, the examiner can find no known utility for medically efficacious substances which are not even released. Given that applicant's invention contravenes established scientific principles and depends upon principles alleged but not generally recognized, applicant's disclosure, submissions, and rebuttals to date fail to overcome the lack of utility rejection. *Applicant argues that reference of MacKinnon teaches that the proximity of ions to ion channels activates electrical signals.* This is not found persuasive since McKinnon is discussing the interaction of hydrated ions with the ion channels which is not analogous to applicant's invention wherein the medically efficacious substance is not released. In fact, given the central importance of the interaction of the hydrated ions and the remarkable capacity of ion channels to distinguish between even sodium and potassium ions, the teachings of McKinnon support the examiners conclusion that the applicant's invention contravenes established scientific principles and depends upon principles alleged but not generally recognized. *Applicant argues*

that the aspirin is first hydrolyzed to salicyclic acid and is therefore capable of dissolving in water and therefore has ionic properties. This is not found persuasive because if the salicylic acid is not even released it does not have any utility. As the examiner has already mentioned, the known use of aspirin and related compounds is via their interaction with COX receptors. Since the salicylic acid in applicant's invention is not released it cannot interact with the COX receptor and does not have a credible utility.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
>
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 7-11, 24-28, 30-33, and 35-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained. Newly added claim 37 is also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement too.

The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention. The specification does not reasonably provide enablement for how to use the claimed preparation or composition for the treatment of diseases. Applicant does not provide adequate evidence to substantiate the fact that a drug coated such that the drug that is

prevented from release is surly effective. Applicant provides no evidence to substantiate the assertion that a drug which is not released is effective at treating any diseases.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope of breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

Scope or breadth of the claims

The breadth of the claim is a medically efficacious substance which is coated with a liquid impermeable but gas permeable layer such that the medically efficacious substance is prevented from release.

Nature of the invention

The nature of the invention is directed to the treatment of blocked or malfunctioning exocrine glands using a medically efficacious substance coated in a liquid impermeable but gas permeable layer.

Relative level of skill possessed by one of ordinary skill in the art

The relative level of skill possessed by one of ordinary skill in the art of medical research is relatively high, as a majority of lead investigators conducting scientific research and development in this particular area possess M.D. and/or Ph.D. in a scientific discipline such as medicinal chemistry, biochemistry, pharmacology, biology, organic synthetic chemistry or the like.

State of, or the amount of knowledge in, the prior art

The art teaches the coating of drugs or other medically efficacious substances for controlling the release of the drug. Coated drugs are well known and include, e.g., aspirin (US patent 4508702, abstract); applicant teaches the use of coated aspirin in example 3 in the specification. The prior art does not recognize the treatment of diseases with drugs which are never released.

Level or degree of predictability, or a lack thereof, in the art

Currently, there are well established methods of coating drugs. Specifically, the use of polymers, ceramics and waxes including natural wax and beeswax for coating drugs are known in the art (US Patent No 5827538, see the whole document). However, even drugs coated with polymers, ceramics and waxes including natural wax and beeswax are designed for the controlled release of the encapsulated drug. No prior art, however, teaches a coated drug which is not released upon administration. Moreover, there is no prior art that predicts that such a drug which is not released would be efficacious.

Presence or absence of working examples

The specification fails to provide scientific data and working examples with respect to the effectiveness of the coated drugs which are not released. The information provided in the

examples does not meet the currently accepted scientific standards for determining the efficacy of new pharmaceutical compositions. The currently accepted practice uses double blind controls in which one group receives the new drug and a control group receives a placebo; neither group knows whether it receives a placebo or the new drug being tested. The examples given in the specification do not have control groups. Moreover, patients know when they are receiving the ActivSignal form versus the standard form of the drug. Additionally, the agitation of coated medically efficacious substances in acidic or alkaline water is inadequate to justify the assertion that the coating is impermeable to liquids generally. It is also inadequate to ensure that the medically efficacious substance is not released upon administration to the subject since acidic and basic water do not adequately simulate all biological fluids that might be encountered by the coated medically efficacious substance upon administration to a subject. Moreover, applicant fails to specify the acid or base used and the pH of the resulting solution.

Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation to reasonably and accurately determine whether the composition of the instant application is not released and moreover to determine whether a drug which is not released is effective.

Response to Arguments

Applicant's arguments filed on 4/5/2010 have been fully considered but they are not persuasive. *Applicant traverses for at least the reasons set forth previously for the record.* The examiner has responded to those arguments previously so incorporates the rebuttal arguments by

reference in this section too. *Applicant argues that in his declaration dated 4/5/2010 Mr. Warren Ward states that spheres enclosing sodium chloride constructed according to one or more embodiments of the claimed invention does affect its immediate surrounding environment without the preparation of the invention being changed in any way.* This is not found persuasive since there is no indication that the sodium chloride is at all relevant to the alleged action on the metals. The comparison experiment was with dissolved sodium chloride. Comparison studies with spheres either lacking a medically efficacious substance or with a different medically efficacious substance do not appear to have been performed. Moreover, applicant has not explained how facilitating corrosion of metals is a substantial utility of the instantly claimed invention or how corrosion of metals is related to the utility of the instantly claimed invention as a medicament.

The rejection of claims 7-11, 24-28, 30-33, and 35-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained. Newly added claim 37 is also rejected under35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention too.

The examiner was unable to ascertain the meets and bounds of the claimed invention because as written the claims are vague and indefinite. The claim language recite a preparation for use as a medicament, wherein the agent is prevented from release and dependant claims also recite known pharmaceutical forms such as a tablet, a capsule etc. It is not clear whether the

instantly claimed invention is pharmaceutical formulation since the medically efficacious substances is prevented from being released. The claims as written, therefore, are unsearchable. Therefore, the examiner still did not apply any art in the rejection of the claimed invention.

Response to Arguments

Applicant's arguments filed on 4/5/2010 have been fully considered but they are not persuasive. *Applicants argue that the claimed preparation does not have to be a pharmaceutical, nor does the claimed preparation depend on release of the encapsulated substance for therapeutic action.* This is not found persuasive since medicament and pharmaceutical are synonyms as evidenced by Thesaurus.com.

Conclusion

Claims 7-11, 24-28, and 30-33, and 36-37 are rejected. . Claims 1-6, 12-23, and 34 remain withdrawn. Claims 29 and 35 are cancelled. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne P. Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa 6/14/10
/YVONNE L. EYLER/

Supervisory Patent Examiner, Art Unit 1619